DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 24, 2014

Nephros Incorporated
Mr. Jim Summerton
Manager Product Development
41 Grand Avenue
River Edge, NJ 07661

Re: K141731
Trade/Device Name: DSU-H and SSU-H Ultrafilters
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification Device, General Medical Use
Regulatory Class: II
Product Code: NHV
Dated: September 24, 2014
Received: September 26, 2014

Dear Mr. Summerton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141731

Device Name: DSU-H and SSU-H Ultrafilters

Indications For Use:

The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filters aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment 3

005: 510(k) Summary

510(k) Summary: DSU-H and SSU-H Ultrafilters

Submitter:	Nephros Inc. 41 Grand Ave River Edge, NJ 07661 Establishment Registration # 3003337893
Contact Person	Jim Summerton, Manager Product Development 41 Grand Ave River Edge, NJ 07661 201-343-5202 (p) 201-343-5207 (f) summerton@nephros.com
Date Prepared	September 22, 2014
Trade Name	DSU-H and SSU-H Ultrafilters
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification Device, General Medical Use
Product Code	NHV
Predicate Device	MainStream™ Water Purification Device – K012716
Reference Devices	DSU and SSU Filters – K110285
Device Description	The DSU-H and SSU-H Ultrafilters are hollow fiber ultrafilters that retain bacteria, viruses, endotoxin and particulate from water used for washing and drinking.
Intended Use	The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for washing and drinking, the filters aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.

Summary of the Technological Characteristics	The proposed device contains a polysulfone hollow fiber membrane encased in an ABS housing that retains bacteria, viruses and endotoxin. Retention of contaminants is through size exclusion. Further details of the technology can be found in Section 11 'Device Description'.
Assessment of Non-clinical Performance Data / Substantial Equivalence	Based on non-clinical performance testing, the DSU-H and SSU-H Ultrafilters have been found to be substantially equivalent to the predicate PrisMedical MainStream Filter (K012716).

SUBJECT – PREDICATE COMPARISON TABLES

	Subject Device	Predicate Device	Reference Device
510(k) Number	K141731	K012716	K110285
Manufacturer Name	Nephros Inc.	PrisMedical	Nephros Inc.
Indications for Use	The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for washing and drinking, the filters aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.	To produce from EPA grade drinking water, sterile purified water to be used within 24 hours of collection that is suitable for: - Cleaning and rinsing open wounds - Infection control (cleaning equipment used in medical procedures, medical personnel's hands) - Use as a diluent for enteral, nutritional, oral vaccine, or oral drug preparations - All other uses of sterile purified water the practitioner or clinician deems necessary - Not for parenteral administration	The DSU and SSU Filters are intended to be used to filter water or bicarbonate concentrate used in hemodialysis devices. They assist in providing hemodialysis quality water or bicarbonate concentrate. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with other water treatment equipment (RO, DI, etc.).

	Subject Device	Predicate Device	Reference Device
Operation			
Feed Water Source	In-line plumbing	Gravity feed	In-line plumbing
Use Life	up to 3 Mo. (SSU-H) up to 6 Mo. (DSU-H)	3 Liters	1 Year
Maximum Inlet Pressure	75 psi (SSU-H) 100 psi (DSU-H)	< 10 psi	75 psi
Flow Rate and Pressure Drop	See Section 18 for subject device flow curves	30 ml/min at 5 psi	Same as subject device
Materials			
Casing	ABS	Polycarbonate	ABS
Filter Element(s)	Polysulfone Ultrafiltration Hollow Fiber	Ultrafiltration Sheet Membrane Polypropylene mesh Activated Carbon Deionization Resin Beads	Polysulfone Ultrafiltration Hollow Fiber
Retention			
Bacteria Reduction	$> 10^{11}$	$> 10^{7}$	$> 10^{11}$
Virus Reduction	$> 10^{8}$	$> 10^{4}$	$> 10^{8}$
Endotoxin Reduction	$> 10^{5}$	$> 10^{4}$	$> 10^{5}$
Organic Reduction	N/A	TOC reduced to < 1 ppm	N/A
Ion Reduction	N/A	$> 10^{3}$ dissociable ions	N/A